TRANSCRIPT OF RECORD

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1948

No. 640

UNITED STATES OF AMERICA, PETITIONER,

versus

FRED ORBETEIT, CLAIMANT OF 16 ARTICLES OF DEVISE, MORE OR LESS, LABELED "SINUTHERMIC," ETC., RESPONDENTS

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1948

No. —

UNITED STATES OF AMERICA, PETITIONER,

versus

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVISE, MORE OR LESS, LABELED "SINUO-THERMIC," ETC., RESPONDENTS

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

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UNITED STATES OF AMERICA,

UNITED STATES COURT OF APPEALS, FIFTH JUDICIAL CIRCUIT

Pleas and Proceedings had and done at a regular term of the United States Court of Appeals for the Fifth Circuit, begun on the third Monday in November, A. D. 1948, at New Orleans, Louisiana, before the Honorable Samuel H. Sibley, the Honorable Joseph C. Hutcheson, Jr., and the Honorable Edwin R. Holmes, Circuit Judges:

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC", ETC., APPELLANT

versus

UNITED STATES OF AMERICA, APPELLEE

Be It Remembered, That heretofore, to-wit, on the 7th day of July, A. D. 1947, a transcript of the record in the above styled cause, pursuant to an appeal from the District Court of the United States for the Northern District of Florida, was filed in the office of the Clerk of the said United States Court of Appeals for the Fifth Circuit, which said transcript was filed and docketed in said Court of Appeals as No. 12033, and that on the 27th day of December, A. D. 1948 the mandate of the Supreme Court of the United States in said case was duly filed, and that the following proceedings were had subsequent to the filing of said mandate of the Supreme Court, to-wit:

1 *Motion of the United States to Affirm Decree of Condemnation, Filed January 15, 1949*

In the United States Court of Appeals for the Fifth Circuit

No. 12033

FRED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE LABELED "SINUOTHERMIC", ETC., APPELLANT

v.

UNITED STATES OF AMERICA, APPELLEE

Motion to Affirm Decree of Condemnation

The United States of America moves that the decree of condemnation entered by the United States District Court for the Northern District of Florida on January 27, 1947, be affirmed.

Statement of facts

This case was decided in this Court on November 7, 1947. Judgment was entered reversing the decree of condemnation and remanding the case to the district court for proceedings not inconsistent with the Court's opinion (R. 179-183 and 164 F. 2d 245). The reasons for reversal were (1) that the trial court erred in holding that the leaflet "The Road to Health" constituted labeling within the meaning of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(m)]; (2) that the court below erred in refusing to hear the testimony of 30 patients as to "whether their external symptoms abated and their pains ceased" when treated with the machines; and (3) that the trial judge erroneously refused to accept the testimony of Dr. Urbuteit to establish the diagnoses of the patients' diseases and ailments.

2 A petition for certiorari, restricted to the issue whether the leaflet constituted labeling, was granted on April 19, 1948 (R. 185). On November 22, 1948 the Supreme Court of the United States reversed and remanded the case to this Court. (No. 13, October Term 1948, 93 L. Ed. 79). The Court held that the leaflet was labeling within the meaning of the Act. The mandate was returned on December 22, 1948.

Grounds for Affirmance

1. The decree should be affirmed because of labeling representations as to diagnostic capabilities of the machines which all the evidence, including Dr. Urubteit's admissions, shows are false.

The leaflet, "The Road to Health", in part describes the diagnostic capabilities of the machines as follows:

Importance of Examination

You must realize the all importance of being examined the Sinuothermic way, which leaves out all guess work as Sinuothermic locates the cause and registers exactly [p. 1, col. 3].

* * * * * * * * *

Cancel Danger Signal

* * * At the Sinuothermic Institute no one is ever treated without first being thoroughly examined, and it should be remembered that NO really COMPETENT doctor will treat a condition that might be a cancer without first making a caseful examination. INSIST on a thorough examination no matter who your doctor is. Be examined with Sinuothermic which registers exactly and never makes a mistake [p. 1, col. 4].

* * * * * * * * *

3 Be Examined

Why have someone guess at what your ailment is when at the Sinuothermic Institute, Inc., you can be examined with that never failing Sinuothermic machine, which leaves out all guess work and registers exactly [p. 1, col. 4].

Sinuothermic Examination

Dr. Urbeit told them that he could not tell them anything until he examined her with Sinuothermic. The examination revealed that she not only had a tumor in the uterus but she was also pregnant about 5 months. * * * [p. 2, col. 6].

* * * * * * * *

Science At Its Peak

Sinuothermic is the last word in scientific discoveries. Sinuothermic is a tester of human tissue. You could liken Sinuothermic to the tester they use to test your radio tubes with * * * Sinuothermic registers exactly the condition of human tissue p. 2, col. 6.

The general representation that the machine "locates the cause" of any ailment and "registers exactly" appears frequently throughout the leaflet.

The evidence at the trial showed that the Sinuothermic machine consists of a number of electrical units mounted in a wooden cabinet (R. 39). The machine is designed to draw electricity from an ordinary household wall socket, to control the full line voltage (electrical pressure) by turning in variable amounts from zero to the full line voltage (115-120 volts), to step this voltage down to a maximum value of 60 volts, and to deliver current to the patient so that it will flow through the body between two pad electrodes that are applied to the bare skin (R. 39-44, 50-52, 164). The small machines differed from the master units only in the omission of the four indicating meters (R. 43, 164).

The evidence showed, further, that even the master model, which had four indicating meters, was incapable of registering any pathological changes in the body. This was because the meters were primarily affected by the patient's body resistance to electrical current and because internally the current is conducted through body fluids and not body tissues (R. 43, 51-52). The so-called treating units did not have the four indicating meters (R. 43). The expert testimony for the Government was that these machines were without value in the diagnosis of the disease conditions involved (R. 72, 76, 79-80, 83-85, 88-89, 91, 93, 96-97, 99-100, 104-105, 109-112).

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Urbuteit described his method of "diagnosis" as follows: he said that when the current from the machine encounters a lesion in the human body, the meters will register "the amount of intensity or resistance there is in that particular area" (R. 126-127, 128-130). He admitted, however, that the machines alone are incapable of diagnosing any specific disease:

> The meters do not tell me what the ailment is, it merely registers when it is below normal. If it is normal it has a free flow; if it is not normal it has the obstructed flow, and according to the amount of obstruction that also indicates the severity of the ailment itself. Then the doctor, himself, should know from other tests what the ailment is * * *. R. 129.
>
> * * * * * * * * *
>
> * * * There is no way of registering the kind of ailment or the name of an ailment. It merely locates where there is something wrong. Then whatever that something is wrong, it is necessary then to take chemical tests; or whatever tests is necessary to determine the name of the ailment that can also be done. But I find in all my experience it is not necessary to go to all that trouble to take those tests. As long as the patient gets well, that seems to be the first requisite [R. 129-130].

The expert testimony for the Government contradicted this claim that the machine could "locate where there is something wrong" (R. 76, 79-80, 93, 96-97, 99-100, 104-105, 109-112). The trial court found (1) that the leaflets claimed diagnostic capabilities and therapeutic effects for the machines in many conditions (R. 165, Finding 4) and that they represented that the machine will register the exact nature of any disease (R. 165, Finding 5); (2) that the master model was incapable of diagnosing disease by registering pathological changes in the body (R. 165-166, Finding 5); and that the principles on which the machines were claimed to operate were impossible of practical application with these instruments (R. 166, Finding 7). The falsity of the claims of diagnostic capability of the small models was treated under Finding 7. These findings of fact have never been challenged.

The misrepresentations as to diagnostic capacity were established in part by respondent's own admissions. His testimony was that the machines—even the ones that had meters—would not specifically diagnose what the patient's ailment was (R. 129-130). He said that the device "merely locates when there is something wrong." The Government's evidence was overwhelming that the machines could not do even that. This Court, in its opinion, pointed out that Urbuteit's testimony "only claimed the machine to be an aid in diagnos-

ing"; that his testimony was that the machine "did not indicate any particular disease but only located the spot where the abnormal tissue was" after which "it was then a matter of judgment as to what the disease was" (R. 182, 164 F. 2d 245, 247).

The labeling claims are irreconcilable with this testimony. They assert that the machine "leaves out guess work"; that it "registers exactly and never makes a mistake"; and that it removes the necessity of having "someone guess at what your ailment is." Urbuteit's testimony implicitly admitted that those claims are falsehoods. The Government's evidence gave them the lie explicitly. The representations as to diagnostic capacity were false and on this phase of the case alone, the decree of condemnation should be affirmed. Any error in the exclusion of evidence which did not disprove the making of such misrepresentations would not defeat the Government's right to condemnation.

Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are both false and misleading in all respects. Libelant is entitled to a decree of condemnation if it shows that any one of the various claims made in the labeling is either false or misleading in any particular. Section 502(a); *Goodwin* v. *United States*, 2 F. 2d
6 200, 201 (C.C.A. 6); *United States* v. *Six Dozen Bottles * * * Kuriko*, 158 F. 2d 667, 669-670 (C.C.A. 7); and *United States* v. *One Device * * * Colonic Irrigator*, 160 F. 2d 194, 200 (C.C.A. 10).

The evidence which this Court held improperly excluded was offered to prove that claims of therapeutic or curative value made for the machines were true (R. 158-163). It had no relationship to the truth or falsity of claims of diagnostic ability. This Court held that the evidence as to diagnoses was erroneously excluded *because Urbuteit used the machines only as an aid in diagnosing*, and that the patients should have been permitted to state *whether their external symptoms abated and their pains* ceased (R. 182-183, 164 Fed. 2d 247). The admission of the evidence within those limits would have had no bearing upon the capabilities of the machines as instruments for diagnosing disease.

Since it appears from the undisputed testimony and from the admissions of Urbuteit that the machines are incapable of diagnosing specific conditions, and since the machines were represented as having such diagnostic capabilities, a decree of condemnation should be entered irrespective of whether the court below was correct in holding other evidence relating to the curative value of the machines improperly excluded. The appellant was not prejudiced by the exclusion of this evidence and the ruling of the trial court was not reversible error. *Ross Lumber Co.* v. *Hughes Lumber Co.*, 264 Fed. 757, 760 (C.C.A. 5), certiorari denied, 254 U. S. 635; *Nalban-*

tiah v. United States, 54 F. 2d 63, 64 (C.C.A. 7), certiorari denied, 285 U. S. 536; *Jennings v. United States*, 73 F. 2d 470, 471 (C.C.A. 5). Accord: *Holloway v. Dunham*, 170 U. S. 615, 618.

Conclusion

For the foregoing reasons, the appellee respectfully submits that the decree of condemnation should be affirmed.

ALEXANDER M. CAMPBELL,
Assistant Attorney General.

(Signed) GEORGE EARL HOFFMAN,
United States Attorney for the Northern District of Florida.

7 *Opinion of the Court—Filed February 1, 1949*

In the United States Court of Appeals for the Fifth Circuit

No. 12033

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC", ETC., APPELLANT

versus

UNITED STATES OF AMERICA, APPELLEE

Appeal from the District Court of the United States for the Northern District of Florida

(February 1, 1949)

Before SIBLEY, HUTCHESON, and HOLMES, Circuit Judges

BY THE COURT: Our judgment in this case, reported 164 Fed. (2) 245, was reversed in *United States vs. Fred Urbeteit*, U. S. , , and the cause remanded to us for further proceedings in conformity with the opinion of the Supreme Court. The reversal was on the one point, that certain advertising matter shipped separately from any of the machines and held by us for that reason not to have "accompanied" any of them might nevertheless constitute "labeling", if the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones. There were four or five shipments of machines several weeks apart; and only one shipment of advertising. It does not appear whether there was a single
8 interrelated activity in machines and advertising as to each shipment, or as to which shipments. That appears to be a question which should be further investigated.

The Supreme Court did not disturb our former ruling that the district court should have heard all the evidence offered on the question of the falsity of the advertising. We adhere to that ruling. The judgment of the district court is accordingly reversed and the cause remanded for further proceedings in conformity with the opinion of the Supreme Court and with this opinion.

Judgment Reversed.

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9 Judgment

Extract from the Minutes of February 1, 1949

No. 12033

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC", ETC.

versus

UNITED STATES OF AMERICA

This cause having been remanded to this Court for further proceedings in conformity with the opinion of the Supreme Court of the United States;

On consideration whereof, It is now here ordered and adjudged by this Court that the judgment of the District Court of the United States for the Northern District of Florida, be, and the same is hereby, reversed; and that this cause be, and it is hereby, remanded to the said District Court for further proceedings in conformity with the opinion of the Supreme Court and of the opinion of this Court.

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10 *Motion of Appellee and Order Staying Mandate Pending Petition for Certiorari—Filed February 12, 1949*

In the United States Court of Appeals for the Fifth Circuit

Docket No. 12033

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE LABELED "SINUOTHERMIC," ETC., APPELLANT,

vs.

UNITED STATES OF AMERICA, APPELLEE.

Motion for Stay of Mandate

Now comes the United States of America, appellee herein, and respectfully moves the Court for an order staying the mandate until

and including March 15, 1949, and in support of this motion respectfully shows to the Court that the Attorney General of the United States is submitting to the Solicitor General of the United States recommendation for certiorari for review of the opinion of this Court dated February 1, 1949, it appearing that the Circuit Court of Appeals for the Fifth Circuit in its opinion of said date does not conform to the opinion of the Supreme Court of the United States in said cause which held

> "That the movements of machines and leaflets in interstate commerce were a single interrelated activity not separate or isolated ones"

and it appearing that the Circuit Court of Appeals for the Fifth Circuit did not consider the question whether the Government was entitled to affirmance of decree of condemnation because of false character of advertising with respect to diagnostic capabilities of machines.

That the stay of mandate until and including March 15, 1949 is needed so that the Solicitor General of the United States may make the necessary determination, and thereafter until the Supreme Court of the United States disposes of the petition for certiorari.

11 Respectfully moved this 10th day of February, 1949.

UNITED STATES OF AMERICA,
Appellee,
By ALEXANDER M. CAMPBELL,
Assistant Attorney General,
Washington, D. C.
By (Signed) GEORGE EARL HOFFMAN,
United States Attorney,
Pensacola, Florida.

12 United States Circuit Court of Appeals for the Fifth Circuit

No. 12033

FRED URBETEIT, CLAIMANT OF 16 ATICLES OF DEVICE, MORE OF LESS, LABELED "SINUOTHERMIC", ETC., APPELLANT

versus

UNITED STATES OF AMERICA, APPELLEE

On Consideration of the Application of the Appellee in the above numbered and entitled cause for a stay of the mandate of this court therein to enable Appellee to apply for and to obtain a writ of cer-

tiorari from the Supreme Court of the United States, It Is Ordered that the issue of the mandate of this court in said cause be and the same is stayed for a period of thirty days; the stay to continue in force until the final disposition of the case by the Supreme Court, provided that within thirty days from the date of this order there shall be filed with the clerk of this court the certificate of the clerk of the Supreme Court that certiorari petition and record have been filed. It is further ordered that the clerk shall issue the mandate upon the filing of a copy of an order of the Supreme Court denying the writ, or upon the expiration of thirty days from the date of this order, unless the above-mentioned certificate shall be filed with the clerk of this court within that time.

Done at New Orleans, La., this 12th day of February, 1949.

(Signed) E. R. HOLMES,
United States Circuit Judge.

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13 Clerk's Certificate

United States of America,

United States Court of Appeals, Fifth Circuit

I, Oakley F. Dodd, Clerk of the United States Court of Appeals for the Fifth Circuit, do hereby certify that the pages numbered from 1 to 14 next preceding this certificate contain a full true, and complete copy of all the proceedings, including the opinion of the United States Court of Appeals for the Fifth Circuit, in a certain cause in said Court numbered 12033, wherein Fred Urbeteit, Claimant of 16 Articles of Device, more or less, labeled "Sinuothermic", etc., is appellant, and United States of America is appellee, as full, true and complete as the originals of the same now remain in my office, said proceedings, etc., being filed subsequent to the filing of the Mandate of the Supreme Court of the United States in said case in said Court of Appeals.

In testimony whereof, I hereunto subscribe my name and affix the seal of the said United States Court of Appeals, at my office in the City of New Orleans, Louisiana, in the Fifth Circuit, this 16th day of February, A. D. 1949.

OAKLEY F. DODD,
Clerk of the United States Court of Appeals, Fifth Circuit.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1949 826414 439